REMARKS

The Office Action dated November 12, 2008, has been received and carefully considered. Reconsideration of the outstanding rejections in the present application is respectfully requested based on the following remarks.

I. THE OBVIOUSNESS REJECTION OF CLAIMS 1-21 AND 23-30

On page 9 of the Office Action, claims 1-21 and 23-30 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 3,675,640 to Gatts (Gatts) in view of U.S. Patent No. 6,650,932 to Menzie et al. ("Menzie") and further in view of U.S. Patent No. 5,835,384 to Lin ("Lin"). This rejection is hereby respectfully traversed.

Under 35 U.S.C. § 103, the Patent Office bears the burden of establishing a prima facie case of obviousness. In re Fine, 837 F.2d 1071, 1074 (Fed. Cir. 1988). There are four separate factual inquiries to consider in making an obviousness determination: (1) the scope and content of the prior art; (2) the level of ordinary skill in the field of the invention; (3) the differences between the claimed invention and the prior art; and (4) the existence of any objective evidence, or "secondary considerations," of non-obviousness. Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966); see also KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727 (2007). An "expansive and flexible

approach" should be applied when determining obviousness based on a combination of prior art references. KSR, 127 S. Ct. at 1739. However, a claimed invention combining multiple known elements is not rendered obvious simply because each element was known independently in the prior art. Id. at 1741. Rather, there must still be some "reason that would have prompted" a person of ordinary skill in the art to combine the elements in the specific way that he or she did. Id.; In re Icon Health & Fitness, Inc., 496 F.3d 1374, 1380 (Fed. Cir. 2007). Also, modification of a prior art reference may be obvious only if there exists a reason that would have prompted a person of ordinary skill to make the change. KSR, 127 S. Ct. at 1740-41.

The Examiner asserts that Menzie discloses "collecting second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals," as claimed. However, Menzie issued November 18, 2003, from U.S. Patent Application No. 09/750,683, filed May 15, 2000. Thus, Menzie has an effective filing date of May 15, 2000.

Applicants again respectfully submit that the invention disclosed and claimed in the present application was conceived prior to May 15, 2000. Applicants also respectfully submit that they were duly diligent in preparing and filing the present application from the date of conception of the invention

disclosed and claimed in the present application to the filing date of the present application (i.e., November 20, 2001). Applicants have supported and continue to support the above-stated submissions with inventor declarations under 37 C.F.R. § 1.131 and supplemental inventor declarations under 37 C.F.R. § 1.131, which contain a showing of facts that clearly establish the above-stated submissions.

At this point it should be noted that the actual date of conception need not be provided (and may be redacted, as Applicants have done) in a declaration, but actual dates of diligence must be provided (which Applicants have provided) (see MPEP 715.07).

In view of the foregoing, Applicants respectfully submit that Menzie is not a proper prior art reference for application against the claims of the present application.

Moreover, regarding claims 1, 11, 19, 24, and 25, the Examiner asserts that the claimed invention would have been obvious in view of Gatts, Menzie, and Lin. Applicants respectfully disagree.

Regarding Gatts, Applicants respectfully submit that Gatts relates to an individual patient's health testing and operational procedure of a dynamic health evaluation system. In contrast, the present application relates to a decision analysis system that tracks comparative patient data over time (e.g.,

months or years) in order to draw inferences about the quality of the clinical care provided by ambulatory surgery centers in the out-patient surgery environment. More specifically, Gatts fails to disclose, or even suggest, collecting outcomes data sets associated with a medical procedure for a plurality of individuals (e.g., patients), as set forth in independent claims 1, 11, 19, 24 and 25. Rather, Gatts discloses a dynamic health evaluation system for collecting an individual's health data. Furthermore, Gatts discloses collecting a single patient's health data during a single visit. In contrast, the present application claims collecting ***multiple*** outcomes data sets for one or more indicators associated with one or more medical procedures for a ***plurality*** of individuals in ***multiple*** periods of time via one or more user interfaces located at one or more user entities. Also, Gatts fails to disclose, or even suggest "a medical procedure," as recited in independent claims 1, 11, 19, 24 and 25. In contrast, Gatts merely discloses modifying dynamic treatment of an individual patient in accordance with the monitored data and to provide an optimized level of reconditioning therapy, and fails to disclose "a medical procedure."

Applicants also respectfully submit that Gatts fails to disclose, or even suggest, a method for collecting and reporting outcomes data for benchmarking medical procedures comprising

"establishing a norm based at least in part on an outcomes data group, wherein the outcomes data group comprises a plurality of the first outcomes data sets," as recited in independent claims 1, 11, 19, 24 and 25. The Examiner relies on the abstract of Gatts to disclose "establishing a norm based at least in part on an outcomes data group," as claimed. However, Applicants respectfully submit that the Examiner erred in interpreting the abstract of Gatts. In contrast, Gatts simply discloses a computer programmed to compare a given individual against a preestablished norm. Specifically, Gatts discloses that the computer establishes how a specific individual should perform if he were in good physical and cardiopulmonary health by comparing the individual's data with clinical data stored in a memory bank. *See*, column 3, lines 3-12. Therefore, Gatts discloses providing a preestablished norm from a memory bank and not "establishing a norm based at least in part on an outcomes data group," as claimed.

Furthermore, the Examiner asserts, and Applicants agree, that Gatts fails to disclose, or even suggest, "collecting second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals," as claimed. The Examiner relies on column 2, lines 10-18, and column 3, lines 65-67, of Menzie to disclose such claimed limitation. Applicants

respectfully disagree. Specifically, Applicants respectfully submit that even if Gatts were to be combined with Menzie, the resulting combination would nevertheless fail to show each and every recitation of the claims. Specifically, Menzie discloses that collection devices 14a-14n are operable to measure physiological signals of a patient which are processed to provide a corresponding test result. Also, Menzie discloses that a trained analyst located at the processing center 20 may analyze the physiological data of the patient and the test results may remain at the processing center 20 for viewing over a web browser. *See*, e.g., column 4, lines 1-15. Thus, Menzie simply discloses collecting an individual patient's physiological data via collection devices 14a-14n and storing the physiological data at the processing center 20, but does not disclose "collecting second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals," as claimed.

Assuming arguendo that Menzie does disclose "collecting second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals," as alleged by the Examiner, Applicants further respectfully submit that it would not have been obvious to one of ordinary skill in the art at the time the

invention was made to combine Gatts and Menzie. Indeed, Applicants respectfully submit that Gatts would teach away from Menzie under such an assumption. Specifically, Gatts discloses a dynamic health evaluation (DHE) system that illustrates what a specific person's physical performance capacity should be when evaluated against sufficient known clinical dynamic performance data. Simultaneously, the dynamic health evaluation (DHE) system prints out a proposed curve of performance for that same individual as if he were in a normal state of health. *See*, column 3, lines 13-23. Also, Gatts discloses that additional functions of the dynamic health evaluation (DHE) system may include comparing a curve of an individual's own performance and a theoretical curve of a similar individual in optimum physical condition and producing a recommended reconditioning level designed in terms of intensity, frequency, and duration to systematically program this patient to an optimum state of physical capacity that is consistent with his age and general health. *See*, column 3, lines 39-47. Meanwhile, Menzie would simply disclose a plurality of collection devices 14a-14n operable to measure physiological signals of a plurality of patients, as alleged by the Examiner. *See*, column 4, lines 1-3. Therefore, Applicants respectfully submit that it would not have been obvious to one of ordinary skill in the art at the time of the invention was made to collect and store physiological data

from a plurality of individuals as allegedly disclosed by Menzie in order to evaluate an individual patient's physical condition as disclosed by Gatts.

Lastly, Applicants additionally respectfully submit that Gatts and Menzie, either alone or in combination, fail to disclose, or even suggest, a medical benchmarking system for multiple medical facilities (e.g., user entities and surgical centers), as claimed. Indeed, Gatts and Menzie, either alone or in combination, fail to disclose, or even suggest, a medical benchmarking system for multiple medical facilities (e.g., user entities and surgical centers) in any manner. In contrast, the present patent application claims a medical benchmarking system for multiple medical facilities (e.g., user entities and surgical centers) wherein an outcomes monitoring report is generated comparing an outcomes result for a selected medical facility (e.g., a user entity or surgical center) to a norm based upon outcomes from multiple medical facilities (e.g., user entities and surgical centers). See, e.g., claims 1, 8, and 9. Thus, the present patent application is directed toward benchmarking a selected medical facility (e.g., a user entity or surgical center) against multiple other medical facilities (e.g., user entities and surgical centers). The present patent application also claims the broader application to any unit of observation (e.g., patient) for any type of activity (e.g.,

procedure) for any outcome (e.g., indicator) across any medical facility (e.g., ambulatory surgery center). Gatts and Menzie, either alone or in combination, clearly fail to disclose, or even suggest, such claimed features.

At this point, Applicants would like to emphasize to the Examiner that, as stated in MPEP § 2141.02, a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). As confirmed in MPEP § 2145, it is improper to combine references where the references teach away from their combination. In re Grasselli, 713 F.2d 731, 218 USPQ 769, 779 (Fed. Cir. 1983).

In view of the foregoing, it is respectfully submitted that claims 1, 11, 19, 24, and 25 are allowable over Gatts, Menzie, and Lin, either alone or in combination.

Regarding claims 2-10, 12-18, 20, 21, 23, and 26-30 these claims are dependent upon independent claims 1, 11, 19, 24, or 25. Thus, since independent claims 1, 11, 19, 24, and 25 should be allowable as discussed above, claims 2-10, 12-18, 20, 21, 23, and 26-30 should also be allowable at least by virtue of their dependency on independent claims 1, 11, 19, 24, or 25. Moreover, these claims recite additional features which are not

disclosed, or even suggested, by the cited references taken either alone or in combination.

In view of the foregoing, it is respectfully requested that the aforementioned obviousness rejection of claims 1-21 and 23-30 be withdrawn.

II. CONCLUSION

In view of the foregoing, it is respectfully submitted that the present application is in condition for allowance, and an early indication of the same is courteously solicited. The Examiner is respectfully requested to contact the undersigned by telephone at the below listed telephone number, in order to expedite resolution of any issues and to expedite passage of the present application to issue, if any comments, questions, or suggestions arise in connection with the present application.

To the extent necessary, a petition for an extension of time under 37 CFR § 1.136 is hereby made.

Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account No. 50-0206, and please credit any excess fees to the same deposit account.

Respectfully submitted,

Hunton & Williams LLP

By: _____
Thomas E. Anderson
Registration No. 37,063

TEA/DD

Hunton & Williams LLP
1900 K Street, N.W.
Washington, D.C. 20006-1109
Telephone: (202) 955-1500
Facsimile: (202) 778-2201

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